"To assess a modified reporting format for Donor Hemovigilance against the prescribed reporting format prescribed by Hemovigilance Program of India (HvPI) at a blood bank in an Institute of National Importance in Central India"

Thesis submitted to the faculty of

ALL INDIA INSTITUTE OF MEDICAL SCIENCES,

BHOPAL

For the award of the degree of MD in

Transfusion medicine and Blood bank

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CERTIFICATE

This is to certify that the thesis entitled "**To assess a modified reporting format for Donor Hemovigilance against the prescribed reporting format prescribed by Hemovigilance Program of India (HvPI) at a blood bank in an Institute of National Importance in Central India**" is a bonafide and genuine research carried out by **Dr. Aakriti Puri** under the guidance and direct supervision for the award of MD degree.

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I hereby declare that the thesis entitled "**To assess a modified reporting format for Donor Hemovigilance against the prescribed reporting format prescribed by Hemovigilance Program of India (HvPI) at a blood bank in an Institute of National Importance in Central India**" is a bonafide and original work carried out by me under the guidance of Dr. Pratul Sinha, Additional Professor, Department of Transfusion Medicine and Blood Bank, AIIMS Bhopal. The thesis or any part thereof has not formed the basis for the award of any degree/fellowship or similar title to any candidate of any university to the best of my knowledge.

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ACKNOWLEDGEMENT

I dedicate this thesis to my parents, all my teachers and patients, who made this journey possible. I am ever grateful to my parents who taught me to constantly strive to be a better human being. I take this opportunity to thank our Honourable Director, the Dean Academics, all members of the Thesis Review Committee and the Institutional Human Ethics Committee for permitting me to pursue this research work. I am incredibly grateful to my guide Dr Pratul Sinha, Additional professor, Department of Transfusion Medicine & Blood Bank, AIIMS Bhopal for his constant support, insightful comments, mentorship, and understanding during my P.G program and completing my study. I am also thankful to my co guide Dr Vilasini Patil Assistant Professor, Department of Transfusion Medicine & Blood Bank, AIIMS Bhopal for her kind suggestions during my study period. Their dynamism, vision, sincerity and motivation have deeply inspired me. They taught me the methodology to carry out the research and to present the research works as clearly as possible. I express my gratitude to my seniors Dr Devesh Dubey, Dr RishiRaj Sinha, Dr Snehashish Mishra, Dr Vikrant Sharma, Dr Rut Naik, My Co- PG Dr Surbhi Gupta , and My juniors Dr Niranjhana Sree & Dr Aishwarya for their support in my study . I would like to extend my thanks to my friend Dr Suprateek Saha who supported me throughout my thesis. I am thankful to all the nursing staff of Departments of Transfusion Medicine and Blood Bank, for their kind support and cooperation throughout this work. Most importantly, I thank all my donors for being a part of this noble cause. "When we acknowledge that all of life is sacred and that each act is an act of choice and therefore sacred, then life is a sacred dance lived consciouslyeach moment. When we live at this level, we participate in the creation of a better world."- Scout Cloud Lee

-Dr. Aakriti Puri

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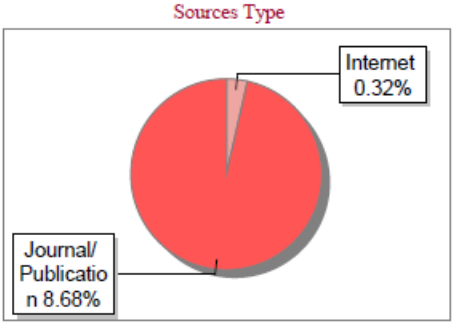
Submission Information

Author Name	Aakriti
Title	Thesis
Paper/Submission ID	1026055
Submission Date	2023-10-14 15:36:26
Total Pages	45
Document type	Thesis

Result Information

Similarity 9 %

Sources Type



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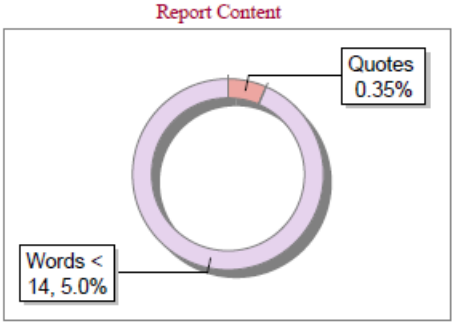

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APPENDIX III: LIST OF ABBREVIATIONS

HvPI	HEMOVIGILANCE PROGRAM OF INDIA
CDSCO	CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
HCV	HEPATITIS C VIRUS
HIV	HUMAN IMMUNODEFICIENCY VIRUS
HBsAg	HEPATITIS B SURFACE ANTIGEN
ISBT	INTERNATIONAL SOCIETY OF BLOOD TRANSFUSION COUNCIL
SHOT	SERIOUS HAZARDS OF TRANSFUSION
PVPI	PHARMACOVIGILANCE PROGRAM OF INDIA
IHN	INTERNATIONAL HEMOVIGILANCE NETWORK
ARC	INTERNATIONAL HEMOVIGILANCE NETWORK
NBDVP	NATIONAL BLOOD DONOR VIGILANCE PROGRAM
NIB	NATIONAL INSTITUTE OF BIOLOGICALS
TRRF	TRANSFUSION REACTION REPORTING FORM
VVR	VASOVAGAL REACTION
MCE	MAJOR CARDIOVASCULAR EVENT
PPTA	PLASMA PROTEIN THERAPEUTICS ASSOCIATION

IEC	INFORMATION, EDUCATION, AND COMMUNICATION

INTRODUCTION

Hemovigilance is defined as a set of surveillance procedures covering the whole transfusion chain, from the collection of blood and its components to the follow-up of its recipients, intended to collect and access information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence.. (1). Increasing the safety of blood transfusions is the ultimate aim of a hemovigilance system.

Blood donations and donors are the foundation of hemovigilance. In order to stop such situations from happening or from happening again, it must make it possible to gather data on the reactions that take place during the donation of blood and the selection of donors. Whole blood donation is generally considered a safe and uncomplicated procedure, but occasionally, donors experience adverse reactions of variable severity during or at the end of collection. Despite complications rates of blood donations being relatively low, donor complications are an important problem, not only for donors but also for transfusion medicine in general, as some complications may negatively affect donor recruitment and retention.

Among Asian countries, a well established hemovigilance system is lacking and there is paucity of data on hemovigilance except for japan , which has published a report on adverse reactions . The study was concerned about post-donation off-site adverse reactions of Japanese volunteer blood donors. Their goal was to collect answers to their postcard questionnaire from 100,000 blood donors who donated 400 ml of whole blood without any on-site problems. The donors were asked to return the postcards within 48 h. The rate of adverse reactions in their study was 2.8%. They also suggested that blood centers have long underestimated the risks of vaso-vagal reactions. (24)

The Blood Bank at All India Institute of Medical Sciences Bhopal is registered as a participant under the Hemovigilance Program of India (HvPI). The HvPI provides a reportable format along with a list of symptoms that indicate adverse reactions in blood donors. The blood bank has been gathering data using this reporting format since January 2019 in order to report and assess adverse responses among blood donors.

THE EXTENT, AND IMPORTANCE OF HEMOVIGILANCE -

All protocols and procedures utilized throughout the transfusion process, from blood donation, processing, and transfusion to donor monitoring, reporting, and investigation of unexpected reactions and events, as well as near misses connected to blood transfusion, should ideally be included in the hemovigilance system. Effective collaboration is required between the blood transfusion service, hospital staff, transfusion laboratories, transfusion committees, regulatory agencies, and national health organizations. An adverse reaction occurs when a negative event results in morbidity or death for the recipient; a complication occurs when it affects the donor. (15).

Following the discovery of an adverse reaction in a blood donor, the donor's safety and care become the top priorities. The time and effort needed to gather information and other essential aspects take a backseat. This impacts the completeness and correctness of the data, which has an impact on the secondary assessment of the data under the hemovigilance program..

The key objectives outlined in the HvPI are (15)

(i) monitor transfusion reactions

(ii) create awareness among health-care professionals

(iii) generate evidence-based recommendations

(iv) advise the Central Drugs Standard Control Organization (CDSCO) for safety-related regulatory decisions

(v) communicate findings to all key stakeholders

(vi) create national and international linkages.

The already available HvPI format for reporting donor reactions is extensive and lacks the provision to monitor the technical donor events that might happen during donation process. In this light, this study is designed to to assess a inhouse reporting format for Donor Hemovigilance against the prescribed HvPI reporting format prescribed by Hemovigilance Program of India (HvPI) at a blood bank in an Institute of National Importance central India.

REVIEW OF LITERATURE

The term hemovigilance is derived from the Greek word 'hema" = blood and the Latin word and 'vigilans" = watchful. Hemovigilance is defined as a set of surveillance procedures covering whole transfusion chain from the collection of blood and its components to the follow up of its recipients, intended to collect and access information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence. (2) Thus, the ultimate goal of a hemovigilance system is to improve the safety of blood transfusion.

Attempts were made to transfuse human blood with animal blood for a variety of illnesses in the 17th century. Because it was thought to be dangerous and lethal, French King Louis XIV formally outlawed the transfusion of animal blood to humans in the eighteenth century. (10).

Henri Leacock and James Blundell investigated inter-human transfusion as a life-saving treatment for acute blood loss for the first time in the 19th century. But because the surgery was also dangerous, Blundel suggested using this therapy only as a last resort, an ultimatum, and after all other treatment options had failed.. The need for safe blood transfusion was felt as early as 1980`s and 1990’s when many hemophilia donors in the UK, France, Canada, Japan, and USA contracted HCV and HIV from blood transfusions and factor concentrates. This emphasized the need to have a haemovigilance programme. (3,12)

> The revolutionary work on hemovigilance started in France in 1991, with the setup of monitoring systems by Blood Transfusion Committees. Since 1993, multiple definitions of hemovigilance have been formulated differing from one country to another. In some countries, only focus was laid on the transfusion act, while in other countries hemovigilance started from the very first part of the blood collection process. (13)

Further, some systems focused on the follow-up of only immediate adverse events, others on long-term adverse events, and few others on both. Because of the complex interactions in the transfusion chain, the scope of hemovigilance is all levels of potential transfusion hazards, i.e. from the selection of potential donors to the transfusion to the recipient. (3)

On European level, hemovigilance started around 1995. The European Council published its Resolution of June 2, 1995 and a Communication on "Blood Safety and Self-Sufficiency in the Community" with the aim to improve public confidence in the safety of the blood supply.(4) In the same year and for the first time on ISBT Congresses, at the ISBT 5th Regional (4th European) Congress in Venice, Italy, a hemovigilance symposium

"Hemovigilance procedures in Transfusion Medicine" was organized. The conclusion of this symposium was that hemovigilance should be considered as part of the quality assurance process in transfusion medicine.(4)

In 1996, the European Commission organized at an informal meeting of Ministers of the European Commission in Adare, Ireland, a Colloquium on Blood, which resulted in the document "Blood Safety and Self-Sufficiency: an Agenda for the European Community". Six areas of action were defined and one of them was hemovigilance. (5)

In the United Kingdom, the Serious Hazards of Transfusion (SHOT) scheme was launched. which receives and collates reports of death or complications of transfusion of blood or components on a voluntary confidential basis. In SHOT's first annual report the findings indicated that blood itself is extremely safe, but it draw attention to the need to direct resources towards the development of novel systems to ensure that it is correctly administered.(6).At different countries discussions were organized on the structure of hemovigilance systems (voluntary or compulsory), the required (type of) data, the data on blood donors, the data on the usage of blood components or also on plasma derivatives, and on the security of systems. Additionally, there was a lot of discussion about setting up a website and an information alert system as communication tools. On December 10, 2012, the Indian Pharmacopoeia Commission and the National Institute of Biologicals in Noida, Uttar Pradesh, jointly inaugurated the Hemovigilance Program of India (HvPI) nationwide as a crucial component of PVPI, which is overseen by the Ministry of Health and Family Welfare of the Government of India.(7) It is a systematic, methodical approach designed to track unfavorable events related to blood transfusions and the delivery of blood products.

This program's primary goal was to monitor adverse reactions and episodes associated with the delivery of blood products and transfusions, identify any trends, and suggest the best practices and interventions needed to enhance donor safety and care. A program called Haemo-Vigil was created to gather and examine information about hemovigilance throughout India. The National Institute of Biologicals serves as the focal point for coordination for HvPI. In December 2014, this HvPl's ultimate goal—becoming a member of the International Hemovigilance Network (IHN)—was accomplished.

In the event of an unfavorable reaction or occurrence during whole blood or component donation, blood donor monitoring is equally critical. Because the etiology of the adverse reaction in the donor differs from that in the recipient, it is more complicated. These unfavorable reactions might result from donor selection, management, or donation; these factors could have an immediate effect on the donor or have an impact on the product's quality, which would then have an effect on the recipient. (18)

The C (ARC) initiated a comprehensive donor hemovigilance program in 2003. The ARC data use established criteria and reporting processes to reflect the current dangers associated with blood donation in a model multicenter hemovigilance system. It is difficult to compare various regional blood centers directly because reported reaction rates differed by regional center regardless of donor demographics. (17)

The HvPI guidelines said that from 2017, donors should be vigilant about disclosing negative reactions associated with blood donation. Nevertheless, a donor surveillance program was chosen in light of the HvPI's success.

Thus, on June 14, 2015, World Blood Donor Day, a National Blood Donor Vigilance Program (NBDVP) was launched in Science City Kolkata, West Bengal, India. (8) (26) To record information about adverse reactions or complications associated with blood donation, a one-page Adverse Donor Reaction Reporting Form (ADRRF) has been developed. The form complies with the complications listed in the International Society of Blood Transfusion of Haemovigilance (ISBT) Working Party on Haemovigilance's Standard for Surveillance of Complications Related to Blood Donation by "donor vigilance" working group.

The HvPI-enrolled centers gather information on unfavorable reactions related to blood donation. Through software created internally by the National Institute of Biologicals (NIB) Information Technology section, the data gathered in the ADRRF is subsequently sent to the coordinating center. In order to find trends and suggest best practices and interventions needed to enhance donor safety, this data is gathered and examined. Transfusion medicine experts have previously given transfusion transmitted diseases a great deal of attention due to the high degree of awareness surrounding them, but little progress has been made in reducing avoidable transfusion errors in developing nations. Health workers underreport transfusion errors due to a lack of knowledge and appropriate training about the management of transfusion-related adverse effects. Hemovigilance is plagued by a number of major issues, including underreporting of adverse events and effects due to fear of punishment and retaliation, late reporting, using multiple reporting channels, incomplete information on incident sheets, and failure to report investigation findings. Additionally, there are issues with communicating with blood banks in the public and private sectors, as well as motivating hospitals to notify events and have functional transfusion committees. The system of blood transfusions is also fragmented, and there are issues with understanding and awareness as well as a lack of a culture of reporting adverse events. inadequate training, a lack of skilled labor, and the absence of a single, uniform system shared by the two blood services and no development of evidence-based guidelines.

A comprehensive approach is necessary for developing countries like India to create a well-organized hemovigilance system. An effective hemovigilance system can be established in a nation through a simplified process for data collection at the hospital level utilizing standardized instruments and good coordination at the national level. A properly operating hemovigilance system can provide data that is utilized as a quality indicator for tracking blood safety. It can also

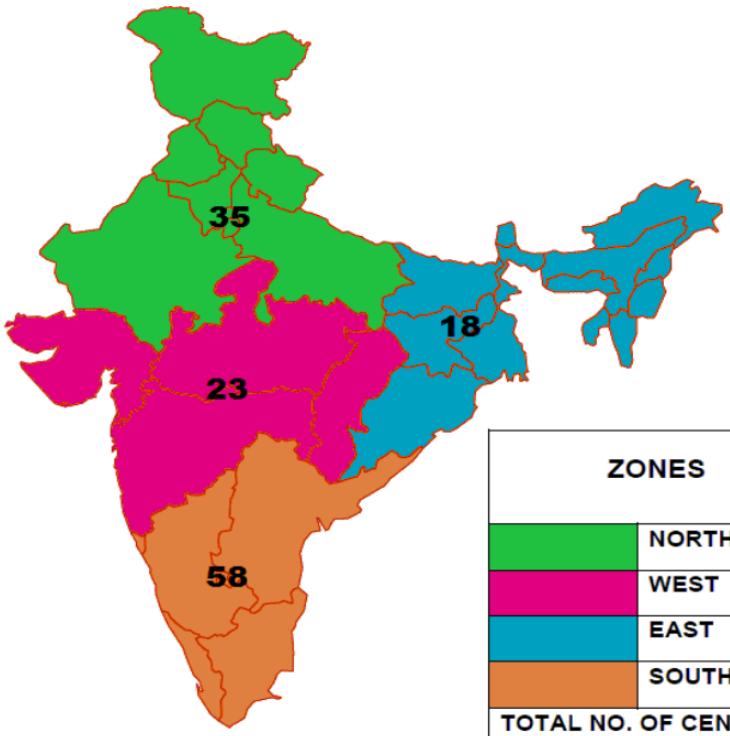
greatly advance evidence-based medicine and aid in the introduction of new blood policies or the revision of current ones. The hemovigilance system needs to be strengthened and made more standard on a global scale.. (9)

India became a member of International Haemovigilance Network (IHN) in December 2014. IHN was established in the Year 2009. India amongst other 33 Countries is one of the members of International Haemovigilance Network. NCC- NIB has participated in General Assembly IHN via webinar on 27th March 2015, wherein an update about Haemovigilance Programme was apprised to the General Assembly IHN. (11)

Presently, 226 centres, located in Blood Banks, Medical Colleges/Institutions, Govt /Private Hospitals are enrolled under this programme. Data in transfusion reaction reporting form (TRRF) from various centres across the country enrolled under HvPI is being collected through a software, Haemo-Vigil indigenously developed by IT Division of NIB. Voluntary reporting is being done with the help of Haemo- Vigil software.

Awareness about the Programme, its objectives and its non- punitive implications is being generated through publications in reputed journals/ magazines & Haemovigilance Newsletters and also by organizing CMEs on HvPI in different regions of the country. During CMEs, hands on training on Haemo-Vigil Software is also imparted to the participants with respect to uplinking Haemovigilance Data in transfusion reaction reporting form (TRRF) via Haemo-Vigil software. (11)

CENTERS UNDER HAEMOVIGILANCE PROGRAM OF INDIA



ZONES	NO. OF CENTERS
NORTH	35
WEST	23
EAST	18
SOUTH	58
TOTAL NO. OF CENTERS	134

Documenting and Reporting of Serious Adverse Reactions/Events in Blood & Blood products Transfusion

Different types of transfusion reactions are subdivided in different ways according to the time of occurrence, pathogenesis and/or symptoms (11)

Classification of Donor adverse reaction

Donor adverse reactions can be classified into 6 broad groups.

A	Local Symptoms 1. Blood Outside Vessel • Haematoma (bruise) • Arterial Puncture • Delayed (bleeding/ Re-bleeding) 2. Arm Pain • Nerve injury / irritation • Other arm pain 3. Localized Infection/ Inflammation along the course of a vein • Thrombophlebitis • Cellulitis 4. Other major blood vessel injury- Serious conditions needing specialist medical diagnosis and attention • Deep Venous Thrombosis (DVT) • Arteriovenous Fistula • Compartmental Syndrome • Brachial Artery Pseudo aneurysm
B	Complications mainly with Generalized Symptoms: Vasovagal Reactions • Without Loss of Consciousness (LOC) • With LOC (Loss of Consciousness) < 60 sec • With LOC (Loss of Consciousness) > 60 sec • With Injury • Without Injury • Within Blood collection facility • Outside Blood collection facility
C	Complications related to Apheresis • Citrate reactions • Haemolysis • Air Embolism • Infiltration • Infiltration of IV fluids
D	Allergic Reactions • Local Allergic Reactions • Generalized allergic Reactions (Anaphylactic Reactions)
E	Serious Complications • Acute Cardiac Symptoms • Myocardial Infarction (MI) • Cardiac Arrest • Transient Ischemic Attack (TIA) • Cerebrovascular Accident • Death
F	Other Reactions

A. Local Symptoms

These DARs are directly caused by the insertion of the needle. Some of these are mainly characterized by the occurrence of blood outside vessels, whereas others are mainly characterized by pain

B. Complications mainly with generalized symptoms: Vasovagal Reactions

A vasovagal reaction (VVR) is characterised by a general sense of discomfort and weakness, as well as anxiety, dizziness, and nausea, which may progress to loss of consciousness (fainting). It can be caused by both physiological and psychological factors. The autonomous nervous system causes the reaction, which is further triggered by psychological factors and the amount of blood removed in comparison to the donor's total blood volume. It can happen before, during, or after donation, and it can happen within or outside the blood donation complex. (20)

C. Complications related to apheresis

i) Citrate reaction- It is a type of neuromuscular hyperactivity caused by a decrease in ionized calcium levels

ii) Haemolysis during apheresis procedure- Donor red cells may get damaged in the return line of the apheresis kit releasing haemoglobin.

iii) Air embolism- Air bubbles are injected into the apheresis donor circulation. Air can enter the apheresis kit tubing due to improper priming of the tubing, equipment failure, faulty kits, or incorrect manipulation by staff. This air can circulate in the pulmonary or arterial circulation, reducing blood flow in the lungs or brain

iv) Infiltration- Intravenous solute (saline, albumin solution) enters the extravascular tissues during volume replacement (can happen during any apheresis procedure like plasmapheresis or even plateletpheresis if the needle is improperly positioned)

v) Unable to return red cells- Due to an emergency termination of the apheresis procedure, red blood cells in the apheresis kit are not returned to the donor. It might be due to technical errors in the equipment or severe donor reaction

D. Allergic reactions- Can be local or Generalised

E. Other serious complications related to blood donation-

F. Major cardiovascular event (MCE)

Grading of Imputability

Imputability refers to the strength of the relation between donation and the adverse reaction. There are 5 groups

Definite or Certain	Conclusive evidence beyond reasonable doubt that donation caused the complication (DAR)
Probable or Likely	Clearly in favor that the donation caused the complication (DAR).
Possible	Evidence is indeterminate that complication adverse reaction (DAR) could be caused by donation or by other reason
Unlikely or Doubtful	Clearly in favor that "other" reason is the cause of the complication (DAR) adverse reaction
Excluded	Conclusive evidence beyond reasonable doubt that reasons other than donation caused the complication (DAR)

Severity Grade Tool

The severity grading subgroup was formed in January 2018 by the AABB Donor Hemovigilance Working Group, the ISBT Donor Haemovigilance Working Group, and the chair of the Plasma Protein Therapeutics Association (PPTA) Medical Policy Committee (representing the source plasma collection industry) to undertake the task of developing the Severity Grading Tool (SGT) for blood donor adverse events. This grading tool assigns severity grades 1-3 with 1 through 3 approximately corresponding to mild, moderate, severe.

Categories	Grade 1	Grade 2	Grade 3
A.1. Blood outside vessel -Haematoma - Arterial puncture - Delayed bleeding	- No OMC - Localized to the venipuncture site	- OMC (EMR, ER, Urgent care), No hospitalization, or - ADL ≤2 weeks, or - Generalized beyond venipuncture site	- Hospitalization, or - ADL -2 weeks, or - Severe sequelae, or - Surgical intervention
A.2. Arm Pain - Nerve injury/irritation - Other arm pain	- No OMC - Duration ≤2 weeks	- OMC (EMR, ER, Urgent care), - No hospitalization, or - Duration -2 weeks to ≤6 months, or - ADL ≤2 weeks	- Duration - 6 months, or - ADL -2 weeks
A.3. Localized infection/inflammation of vein or soft tissue -Superficial thrombophlebitis -Cellulitis	-No OMC	-OMC (EMR, ER, Urgent care), -No hospitalization, or -ADL ≤2 weeks, or -Resolved with oral antibiotics	-Hospitalization, or -ADL -2 weeks, or -Resolved with IV treatment
A.4. Other major blood vessel injury -Deep venous thrombosis -Arteriovenous fistula -Compartment syndrome -Brachial artery pseudoaneurysm			-Diagnosis is medically confirmed, or -Treated with anticoagulant therapy, or -Required surgical intervention
B. Vasovagal reactions -Vasovagal reaction, no loss of consciousness (LOC) -Vasovagal reaction, loss of consciousness (LOC)	-No OMC	-OMC (EMR, ER, Urgent care), -no hospitalization, or -ADL ≤2 weeks, or -Suture of laceration(s), or -IV rehydration	-Hospitalization, or -ADL -2 weeks, or -Fracture(s), medically confirmed concussion, a dental injury requiring dental procedure, e.g., cap/crown, dental implant, bridge, tooth extraction, dentures
C. Related to apheresis -Citrate reaction -Haemolysis -Air embolism -Infiltration	-No OMC -Citrate toxicity (including carpopedal spasm) resolved with or without oral calcium	-OMC (EMR, ER, Urgent care), no hospitalization, or -ADL ≤2 weeks, or -Citrate toxicity requiring intravenous calcium	-Hospitalization, or -ADL -2 weeks, -Abnormal cardiac rhythm medically diagnosed

D. Allergic Reaction -Local allergic reaction -Generalized (anaphylactic) reaction	-No OMC -Managed with over-the-counter medications—topical steroids, antihistamine	-OMC (EMR, ER, Urgent care), no hospitalization, or -Generalized reaction including bronchospasm, Laryngospasm managed with inhalation or oral bronchodilator and/or autoinjector (EpiPen)	-Hospitalization, or -Generalized reaction, including bronchospasm, laryngospasm, or anaphylaxis, requiring management with intravenous steroids and/or epinephrine, but NOT intubation or tracheostomy
E. Other serious complications -Acute cardiac symptoms -Myocardial infarction -Cardiac arrest -Transient ischemic attack -Cerebrovascular accident (Stroke)			-Diagnosis is medically confirmed
F. Other	-No OMC -No injury	-OMC (EMR, ER, Urgent care), no hospitalization, or -Duration -2 weeks to ≤6 months, or -ADL ≤2 weeks	-Hospitalization, or -Duration - 6 months, or -ADL -2 weeks, or -Surgical intervention
OMR: Outside Medical Care, EMR: Emergency Medical Response, HCP: Health Care Professional, ER: Emergency Room, ADL: Activity of Daily Living			

Submission of data in Donor haemovigilance software

The data is submitted in the website for the National Institute of Biologicals on URL:-

http://nib.gov.in/haemovigilance.aspx using User Id and password given by the Haemovigilance Programme of India

Flow of information under HvPI

Private Hospitals, Nursing Homes, Medical Institutions, Medical Colleges
(Collection and follow-up of Transfusion Reaction Related reports; Causality assessment; Reporting through data entry into Haemo-vigil software)
National Coordinating Centre – NIB.
Signal Review Panel, Core Training Panel, Quality Review Panel
Advisory Committee
Core Group
National Coordinating Centre, Indian Pharmacopeia Commission, Ghaziabad
(Forward recommendations of Hemovigilance Advisory committee to DCGI-CDSCO)
DCGI – CDSCO (HQ)
Stakeholders
(Patient health care Professionals, Blood Banks, NACO, SBTC)

ROLES AND RESPONSIBILITIES OF HVPI

Data on adverse transfusion reactions and events are sent to HvPI-NCC, NIB by being input into the "haemovigil" software by the transfusion medicine department, blood bank, hospitals, and medical colleges. HvPI-NCC prepares SOPS, guidance manuals, and conveys recommendations to IPC in addition to reviewing the completeness and quality of the data. The Drug Controller General of India (DCGI)-CDSCO body receives the recommendations of the haemovigilance advisory committee from the IPC in the end. The DCGI-CDSCO is in charge of developing regulatory decisions pertaining to blood and blood product transfusion safety and informing relevant parties.

Additionally, the HvPI unit prepares training materials through the production of a magazine on haemovigilance, information, education, and communication (IEC) literature, and the year-round academic CMEs and awareness programs on haemovigilance in India. The most recent edition of the haemovigilance newsletter states that 206 facilities, including blood transfusion centers, medical schools, and hospitals, have signed up for the program. The NCC has received 2296 transfusion reactions in total, and the India program for hemovigilance has now joined the International Haemovigilance Network (IHN). As a result, the main suggestions for an improved hemovigilance program should include stronger national blood quality and safety measures, a decrease in human error, the hiring of more staff with training, the creation of data standards, and more reporting capabilities.

In a study conducted by Priti D Desai et al. where the authors analyzed the frequency of on-site and off-site adverse donor reactions and its correlation with contributory factors. Donors were contacted telephonically. In their study 8.33% donors experienced adverse reaction. Out of the total reactions, 33% reactions occurred on site whereas 67 % reactions occurred off site. Post

donation follow up was done via telephonic communication which resulted in reporting of off site reactions. (14)

Study conducted by kanchan dogra et al, revealed that majority of reactions were owed to equipment related problems and some were due to technical aberrations. All the events associated with donors were mild. No adverse events were reported with any of the therapeutic plasma exchange. (22)

Subhashish et al conducted an institutional study on donor hemovigilance and analysed the adverse events during donation of blood and blood products. In their study, 25,000 whole blood donations were collected, of which 20,000 were voluntary and 5000 were replacement donors. Adverse events (AE) were recorded in 350 donors. Of the 350 AE's, 280 were pre-syncopal or vasovagal reaction. Syncopal minor reactions observed in 40 cases characterized by transient loss of consciousness, lasting for few seconds. Haematoma formation was observed in 20 donors. Minor events such as tingling, numbers, soreness of arm, local allergy, etc were observed in 7 donors. There were 3 major events one each of convulsion, loss of bladder sphincter control and accidental arterial puncture were noted. (25)

Sheetal et al conducted a donor hemovigilance study for evaluation of adverse reactions to blood donors at a tertiary care teaching hospital. During their study period, total 7970 donors were registered, out of which 53.27% donors have donated their blood in blood camps and 46.72% have in blood bank. Incidence of donor reactions was 1.54%. Incidence of adverse reaction was higher at blood camps (58.53%). Authors found highest number of cases of mild vaso vagal type reactions (53%). Other types of reactions observed were painful arm, hematoma, delayed bleeding, tingling and moderate type of vaso vagal reaction. Authors did not find any major

serious events like convulsion, thrombophlebitis or arterial puncture during study period. It considers that safety of donors was maintained. (27)

In a study conducted by Durba Biswas et al where they evaluated the incidence and analysis of blood donor adverse reactions in eastern India. They observed 576 adverse reactions in 11 371 donors, with significantly higher rate in plateletpheresis [61 in 314 donors] than WB donation. First time (451/4551), replacement (172/2894), female (158/1535) and young donors (18–40 years) (485/7969) were significantly prone to AE. Generalized vasovagal reactions (n = 349) were the commonest AE followed by haematoma. The onset of AE was mainly during postdonation period. Vasovagal reactions were significantly high in first time (P = 0·0001), replacement (P = 0·0001), female (P = 0·0001), young (18–40 years) (P = 0·0001) and low body weight donors (45–54 kg) (P = 0·0001) when compared to repeat, voluntary, male, older and heavier donors. Haematoma was found significantly higher in aphaeresis [P = 0·0001], first time [P = 0·0001] and heavier donors [P = 0·0001] as compared to WB, repeat and low body weight donors. (29)

Rubiya et al studied the adverse donor reactions in whole blood donors in a tertiary care hospital. During their one year study period, a total of 35256 donors donated blood, out of which 1928 (5.5 %) donors experienced donation related adverse effects. Reaction rate among male & female donors were 5.3% (1730/23928) & 8.5 % (198/2328) respectively. Most of the donors 90.6 % (1746/1828) who experienced adverse donor reactions belong to the younger age groups. Age & gender had a significant effect on rate of reaction ($p < 0.0001$). Higher rate of adverse reactions 7.9 % (562/7050) was observed in donors with hemoglobin in the range of 12.5 – 13.4 g/dl. Also Significantly higher ($p<0.01$) rate of adverse reactions was observed among 1st time donors

8.7% (1376/15866), replacement donors 6.6% (1048/15864) & donors who donated blood in outside donation camps 6.1% (426/7052). (30)

Yashaswi et al conducted a study for mandating a dedicated hemovigilance nurse and objectification of imputability levels. They found out that, in total 169 adverse transfusion reaction which were reported in 166 donors and 89 (52.6%) were uplinked. The incident rate was 1 in 1412. They concluded that a dedicated hemovigilance nurses in every centre to aid in accurate data sharing with the National hemovigilance systems. Discrepancies in diagnosis can be mitigated by identification and understanding of ATR through case-based objective approach. Discrepancy in assigning imputability levels to adverse reactions can be minimised by objectifying the scales followed by spreading awareness though campaigns. These initiatives can effectively be aided by the hemovigilance nurse. (28)

Title:

To assess a modified reporting format for Donor Hemovigilance against the prescribed reporting format prescribed by Hemovigilance Program of India (HVPI) at a blood bank in an Institute of National Importance in Central India

Aims & Objectives:

Aims:

1. To improve the efficiency of Hemovigilance Program by increasing the efficacy of capturing data and reporting it.

Objectives:

1. To develop an easy-to-use format for reporting donor related hemovigilance events.

2. To assess the performance of the newly inhouse developed and easy-to-use format for reporting donor hemovigilance events.

Materials & Methods

Methodology

Type of Study:

Prospective study as both formats would be used to collect data over a period of twelve months. As there would not be any follow-up of the adverse reaction in the blood donor hence a single cross-sectional observation would be included as a data entry for the purpose of evaluation in the study.

Study setting:

Collection of data points in prescribed format. Study to be conducted in Department of Transfusion Medicine & Blood bank, AIIMS Bhopal, Madhya Pradesh.

Study Population:

Set of adult population that register as blood donors with the blood bank of AIIMS Bhopal.

Study Duration:

From the May 2022 to July 2023.

Sample size:

The study was conducted for the prescribed period among all blood donors that came to donate blood bank of AIIMS Bhopal or in the blood donation camps organized with the blood bank of AIIMS Bhopal.

The study was conducted for the prescribed period among all blood donors that came to donate blood in the blood bank of AIIMS Bhopal or in the blood donation camps organized with the blood bank of AIIMS Bhopal.

THE PROCESS OF BLOOD DONATION-

- Registration- The donor fills out a registration form and gives their consent to donate.
- Medical check-up- The donor's medical history and lifestyle are asked about, and their temperature, blood pressure, pulse, and hemoglobin are checked.
- Donation- The donor sits comfortably or lies down. Phlebotomy is done and blood is collected.
- Recovery- The donor can enjoy a snack and a drink for 10-15 minutes before resuming their day.

SCREENING

- Blood safety means ensuring that it is safe for the donor to donate blood given current health status as well as that donated blood carries minimal risk of adverse effects for the recipient in terms of matching blood groups and is free of Transfusion Transmissible

Infections (TTIs). TTIs are infections which occur in a recipient of a blood transfusion if the transfused blood contains a pathogen. Many organisms like bacteria, viruses and parasites can be transmitted through blood transfusions.

- The Drugs and Cosmetics Act of India mandates that all blood units that are collected in blood banks for the purpose of transfusion should be screened for the following organisms:
    1. Human Immunodeficiency Virus (HIV)
    2. Hepatitis B and Hepatitis C Virus
    3. Treponema Pallidum (which causes Syphilis)
    4. Plasmodium species (which causes Malaria)
- Blood which is detected as having any of these infections is destroyed to prevent infecting others.

The staff posted in the donor area of the blood bank were oriented towards the process of data collection by the prescribed format of HvPI data which is in use in the blood bank and the modified format that is prescribed to be assessed in this study. The modified format included local and systemic complications in the color coding, so it was easy to capture the data by the staff in the donor area. The another part of my modified format which was technical donor events which was not included in the HVPI format.

Taking the consent

i. All donors who register for blood donation were eligible to be included in the study.

ii. At the end of screening for the fitness of the donors, they were given the option for participation in the study.

iii. If the donor agreed, then the details of the study was explained in local language in which the donor was conversant and all queries were answered.

iv. After the donor was explained the format of the study and questions were answered, the informed consent was taken and included with the records of the blood donor.

v. Consent was taken to call back the donor in case the donor experiences any reaction to blood donation.

There was no change in the process of screening for fitness of blood donors, process of blood collection or post donation care of blood donor.

vi. The donor underwent the same process and care that is being presently done in the blood bank.

vii. There was no change in the process of blood donation.

viii. There was no change in care of the blood donor during blood donation process.

ix. There was no change in care of the blood donor in case any reaction to blood donation is encountered.

x. There was no change in care of the blood donor after the process of blood collection was finished.

xi. Post donation care and observation of donor continued as per present protocol.

In case any donor experienced a reaction during the process of blood donation, the details of the donor reaction were recorded for the Hemovigilance program so that a proper analysis was done to prevent or to treat such donor reaction.

The HVPI format for recording donor reactions

xii. The format prescribed by HvPI and in use in the blood bank presently requires a single person to record the details of the donor, identify and record the features of the episode of the reaction to blood donor, details regarding presenting symptoms, vitals of the donor during the reaction, steps taken to mitigate the reaction experience and relief from symptoms of the reaction, record of vitals after care and nursing of the blood donor to full recovery, analysis and processing of reaction data to classify the reaction before sharing it with the National HVPI program.

xiii. In the present format the collection of these data was done during occurrence of an episode of reaction in the blood donor.

xiv. This duty rests with the phlebotomist in the donor area of the blood bank.

The modified format, developed in house and proposed to be used as an alternative to the HVPI format

xv. Duplication of data that can be captured from other records in the blood bank is excluded from the modified format.

xvi. Rest of the parameters included in the HVPI format are included in the modified format.

xvii. The duty of recording the data is under the supervision of the phlebotomist in the donor are of the blood bank.

The inhouse developed format consisted of color coding of local and systemic reactions, so that the real time symptoms could be captured easily, it was designed in a simplified way which also included technical donor events so that data could be captured more easily.

Comparison of the two reporting formats would be analyzed on the following parameters.

Some of these parameters would be-

a) Completeness of data
b) Accuracy of data
c) Problems encountered in processing of data for classification of adverse reaction.
d) Problems encountered in submission of data to HVPI program software.

xix. Feedback from the users in the blood bank was used to modify the changes in the inhouse developed format to make it more efficient in recording the relevant data, accurately and in as short time as possible.

Intervention-

i. The practice of using the present format for collecting data and recording reactions among blood donors for the Hemovigilance program would be continued.

ii. Modified format for collecting the same data and recording reactions among blood donors for the same Hemovigilance program is to be added.

iii. For the sake of the study and to randomize the data

Inclusion Criteria:

Hemovigilance is a sentinel observation program involves collection and analysis of data pertaining to all donor reactions. All eligible blood donors reporting in the blood bank or any blood donation camp organized by the blood bank of AIIMS Bhopal would be included in the study.

Exclusion Criteria:

Nil (data of all donor reactions that are reported would be analyzed).

Type of Study:

Prospective study as both formats would be used to collect data over a period of twelve months. As there would not be any follow-up of the adverse reaction in the blood donor hence a single cross-sectional observation would be included as a data entry for the purpose of evaluation in the study.

Study setting:

Collection of data points in prescribed format. Study to be conducted in Department of Transfusion Medicine & Blood bank, AIIMS Bhopal, Madhya Pradesh.

Study Population:

Set of adult population that register as blood donors with the blood bank of AIIMS Bhopal.

Study Duration:

From the date of approval to July 2023.

Sample size:

The study was conducted for the prescribed period among all blood donors that came to donate blood bank of AIIMS Bhopal or in the blood donation camps organized with the blood bank of AIIMS Bhopal.

The study is to be conducted for the prescribed period among all blood donors that come to donate blood in the blood bank of AIIMS Bhopal or in the blood donation camps organized with the blood bank of AIIMS Bhopal.

Statistical analysis:

1. Nominal or Categorical variable would be summarized as frequency and percentage.

2. Continuous variables will be summarized as mean, standard deviation and mean difference will be calculated when normally distributed and as median and interquartile range when non-normally distributed.

3. Data will be entered into a standard Microsoft Excel sheet.

OBSERVATION AND RESULTS

The study was conducted in the Department of Transfusion Medicine & Blood Bank of AIIMS, Bhopal. Sample collection was started from May 2022 after receiving the letter of Permission from the institutional ethical committee till July 2023. All donor adverse reactions reported during the study period were included in our study. Data of donor adverse reactions reported were captured according to both the HvPI and the modified inhouse format of reporting of Donor adverse reactions.

During our study period, a total 11384 blood donations were received out of which 95.86% donations were of whole blood and 4.13% was Apheresis donations.

Table 1- Total blood donations received during the study period

	Total donations	**Percentage**
Whole Blood donations	10913	95.86%
Apheresis	471	4.13%
Total Donations	11384	

The majority of donations (95.86%) during the study period consisted of whole blood donations, whereas apheresis donations accounted for 4.13% of the total donations.

Table 2- Total donor adverse reactions reported

Reactions	Number	percentage
Whole blood donors	213	95.08%
Apheresis donors	11	4.9%
Total Donor adverse Reactions	224	

A total 224 donor adverse reactions were reported during the study period. The donor adverse reaction rate was found to be 1.96%.

The majority of donor reactions (95.08%) occurred among whole blood donors, while the remaining 4.92% of reactions were reported among apheresis donors.

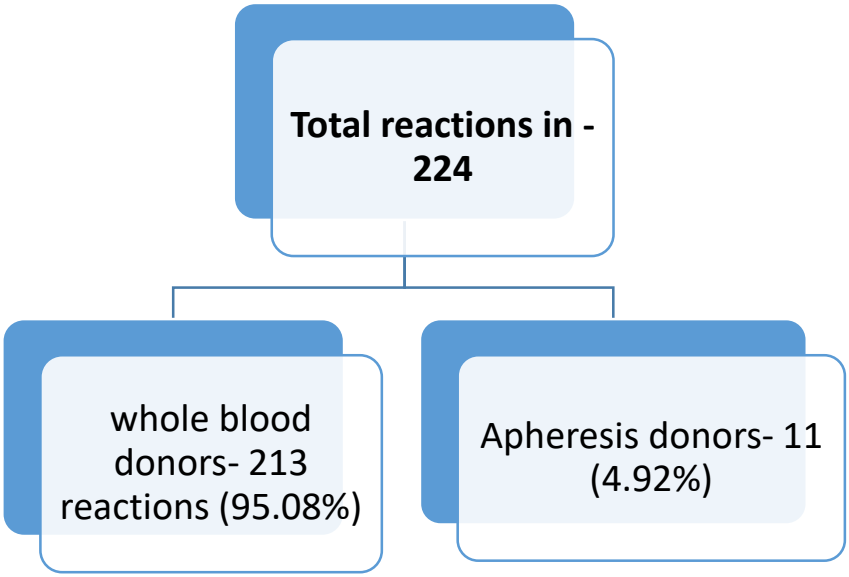


Table 3- Site of donor adverse Reactions

	Reactions reported during in house donation	Reactions reported in outside blood donation camps
Number of donors	184	40
Percentage	82.14%	17.8%

Majority of donor adverse reactions (82.14%) occurred during in-house donations, while a 17.8% of reactions were reported during blood donation camps conducted outside the blood bank facility.

Table 4- Age wise distribution of donor reactions

Age group	**Number of reactions**	**Percentage**
18- 20 years	28	13.2 %
21-30 years	117	52.4%
31-40 years	51	21.7%
41-50 years	13	6.1%
51-60 years	11	5.2%

60-65 years	4	1.4%

52.4% of donor adverse reactions occurred in younger donors, primarily in the 21-30 years age range, followed by 21.7% in 31-40 years group .

Table 5 - Age wise distribution of donor adverse reactions in Whole Blood and Apheresis donors.

Age group	**Apheresis (%)**	**Whole blood (%)**	**Total**
18- 20 years	2 (18.1%)	26 (12.2%)	28
21-30 years	3(27.2%)	114 (53.52%)	117
31-40 years	5 (45.4%)	46 (18.7%)	51
41-50 years	1 (9.09%)	12 (5.6%)	13
51-60 years	0	11 (5.16%)	11
61-65 years	0	4(1.40%)	4
Total	11	213	224

Majority of the donor reactions in whole blood donors were reported in 21 to 30 years of age group followed by 31 to 40 years (114 which amounts to 53.52% of whole blood donors who

developed reactions). However majority of the apheresis reactions were noted in 31 to 40 years of age group (5 in number which amounts to 45.4% of total apheresis donors).

Chart 1- Age wise distribution of study subjects

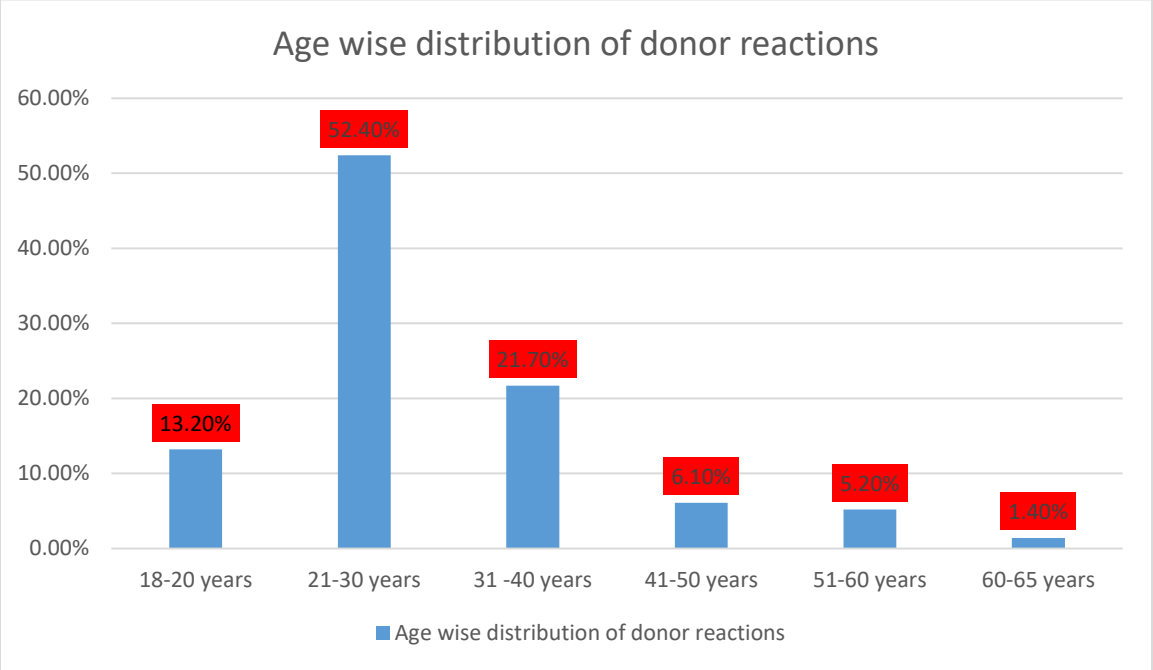


Table 6 : Gender wise distribution of donor adverse reactions

Gender	Number	Percentage
Male	192	85.71%
Female	32	14.2%
Total	224	

In our study, 85.7% of reactions were found in male donors and 14.2 % in female blood donors.

Chart 2- gender wise distribution of all study subjects

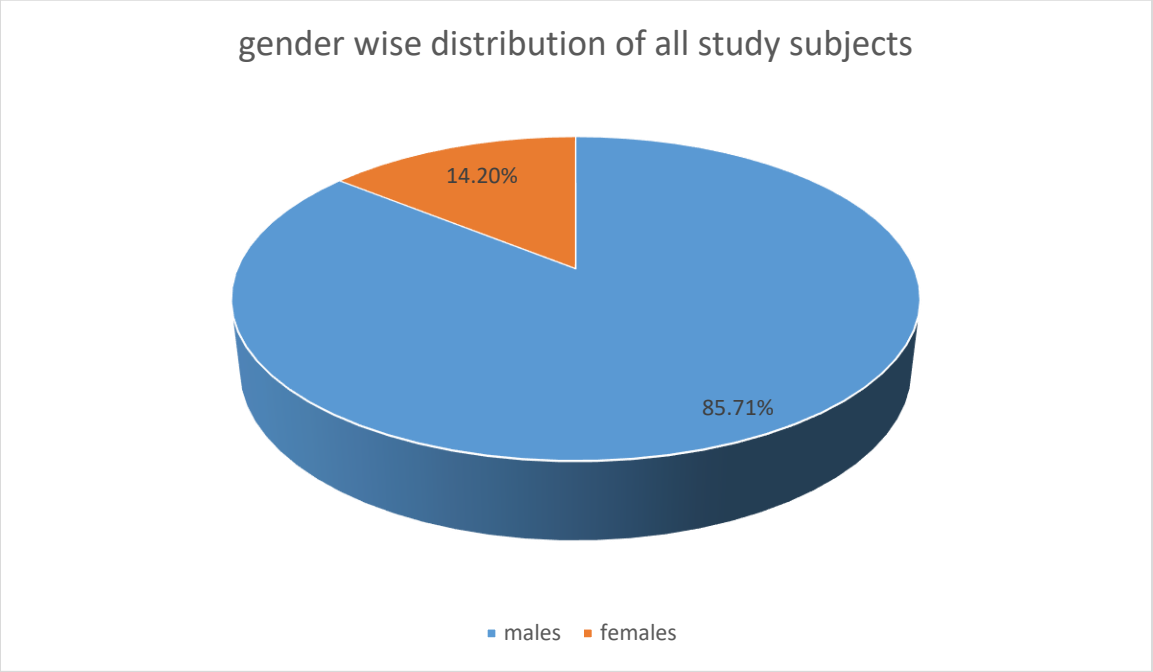


Table.7- Type of donor associated with donor adverse reactions

Type of Donor	**Number of donors**	**Percentage**
First time donor	144	64%
Repeat donor	80	36%
Total	224	

Majority of the reactions were reported in first time donors. First time whole blood donors accounted for 64% of donor adverse reactions whereas repeat donors accounted for 36% of all donors.

Table 8-Type of reactions

Type of reactions	**Number**	**Percentage**
Localized Donor Adverse reactions	59	26.33%
Generalized Donor Adverse reactions	165	73.66%
Total	224	

Out of total 224 donor Adverse reactions reported in our study, 165 donors were generalized reactions. This amounts to 73.66% of total reactions. 59 donors had localized reactions which amounts to 26.33% of total reactions.

Table 9 - Local and Generalized donor adverse reactions in whole blood and Apheresis donors:

	Whole blood donors (%)	**Apheresis donors (%)**	**Total (%)**
Localised Donor adverse reactions	55	4	59 (26.33%)
Generalised Donor adverse reactions	158	7	165 (73.66%)
Total	213 (95.08%)	11 (4.9%)	224

Out of 213 total donor adverse reactions in whole blood donors, 55 cases (25.8%) were localized reactions and 158 cases developed generalized complications (74.17%). In Apheresis donors, 4 cases (36.36%) out of 11 reactions, were localized reactions and 7 out of 11 donors (63.63%) developed generalized reactions.

Table-10- Distribution of Localized donor adverse reactions (n=59)

Local complications	**Whole Blood**	**Apheresis Donors**

	Donors (n=55)	**(n=4)**
Swelling	5 (9.09%)	1 (25%)
Pain	37 (67.27%)	1 (25%)
Color change	10 (18.18%)	0 (0%)
Bleeding	3 (5.45%)	0 (0%)
Tingling	0 (0%)	2 (50%)

Most common localized reactions in whole blood donors reported in our study was pain, which was seen in 37 (67.27%) donors, followed by color change which was seen in 10 (18.18%) donors and swelling which was seen in 5 (9.09%) donors. Most common localized reaction seen in apheresis donors was tingling which was seen in 2 (50%) donors, followed by swelling and pain which was seen in 1 (25%) each.

Table 11- Distribution of Generalized Donor adverse reactions (n=165)

Systemic complications	**Whole Blood Donors (n=158)**	**Apheresis Donors (n=7)**
Sweating	140 (88.60%)	7 (100%)
Weakness	79 (50%)	7 (100%)
Nausea	25 (15.8%)	6 (85.71%)

Feeling cold	12 (7.59%)	0
Speech unclear	5 (3.16%)	0
Vomit	10 (6.32%)	3 (42.85%)
Dizziness	152 (96.20%)	7 (100%)
Incontinence	02 (1.26)	0
Fall	02 (1.26%)	0
Loss of consciousness <60 sec	30 (18.98%)	0
convulsions	3 (1.89%)	0
ghabrahat	98 (62.02%)	0
Rapid pulse	3 (1.89%)	0
Warmth	2 (1.26%)	0

Whole Blood Donors experienced a higher frequency of generalised donor reactions compared to Apheresis Donors. Out of the 165 donors who developed reactions, 158 were whole blood donors and 7 were apheresis donors. Most common generalized systemic reaction noted in whole blood donors was dizziness which was seen in 152 (96.20%) and sweating which was seen in 140 (88.60%), ghabrahat seen in 98 (62.02%), and weakness seen in 79 (50%) donors.

Most common systemic complications seen in apheresis donors was sweating, weakness and dizziness which was seen in all donors. Nausea and vomiting was also common which was seen in 6 (85.71%) and 3 (42.85%) donors.

ITable 12. Comparison of Local complications as per reporting format

Localised Donor Adverse reactions	**HvPI format**	**Modified inhouse Format**
Swelling	6	6
Pain	38	38
Color change	0	10
Redness & warmth	0	0
Itching	0	0
Cellulitis	0	0
Tingling	2	2
Paresthesia	0	0
Bleeding	3	3
Nerve injury	0	0
Rapid filling of the bag	0	0
Symptoms of DVT, arteriovenous fistula,	0	0

compartment syndrome, brachial artery pseudo-aneurysm		
Arterial injury	0	0
Weak pulse	0	0
Hematoma	0	0
Arm pain	0	0
Total	49	59

Localized donor adverse reactions such as swelling, pain, color changes, bleeding, itching, tingling, and rapid filling of the blood collection bag, were subjected to a comparative analysis. The results indicated that the modified inhouse reporting format successfully documented 59 local complications, while the prescibed HvPI format only captured 49 of them. Notably, the inhouse reporting format was effective in identifying specific complications like color change, which remained unrecorded by the prescribed HvPI format. The inhouse reporting format exhibited a higher capture rate of 100% compared to the prescribed HvPI format, which had a capture rate of 83.05% for local complications.

Table 13. Comparison of generalized donor adverse reactions in two formats

Systemic complications	**Prescribed HvPI**	**Inhouse format**

	format	
Pallor	0	0
Sweating	147	147
Palpitations	0	0
Weakness	86	86
Nausea	31	31
Feeling cold/ cold Extremities	12	12
Tingling	0	0
Speech unclear	0	5
Twitching	0	0
Vomit	13	13
Dizziness	159	159
Fall	0	2
Unconsciousness<60 s	30	30
Convulsion	3	3
Tetany	0	0

Incontinence	0	2
Ghabrahat	0	98
Hyperventilation	0	0
Rapid pulse Low volume pulse	3	3
Anxiety*	0	0
Hypotension*	0	0
Warmth	2	0
Total	486	591

‘*’ - anxiety and hypotension were not present in the inhouse format, because the inhouse format was designed to capture symptoms in simple terms like ghabrahat and dizziness.

The modified inhouse format was able to pick up a total of 591 generalized reactions (The number of total donors who developed generalized reaction was 165. However, a single donor can develop more than one systemic complication and were recorded into multiple columns in both the formats) as compared to the prescribed HvPI format which could pick up a total of only 486 reactions. The prescribed HvPI format could not pick up symptoms like gabrahat, fall, unclear speech and incontinence which was successfully picked up by the inhouse developed format.

Table 14.- Technical donor events reported in inhouse format(n=62)

Technical donor events	**No.**	**%**
Associated with reactions	41	66.12%
Not associated with reactions	21	33.87%
Total	62	

During our study period, the inhouse developed format could capture 62 technical donor events, out of which 41 (66.12%) technical donor events were associated with reactions in donors and 21 (33.87%) were not associated with reactions. This data was not picked up by the prescribed HvPI format.

Graph no. 3- Association of technical donor events in study subjects with reactions (n=62)

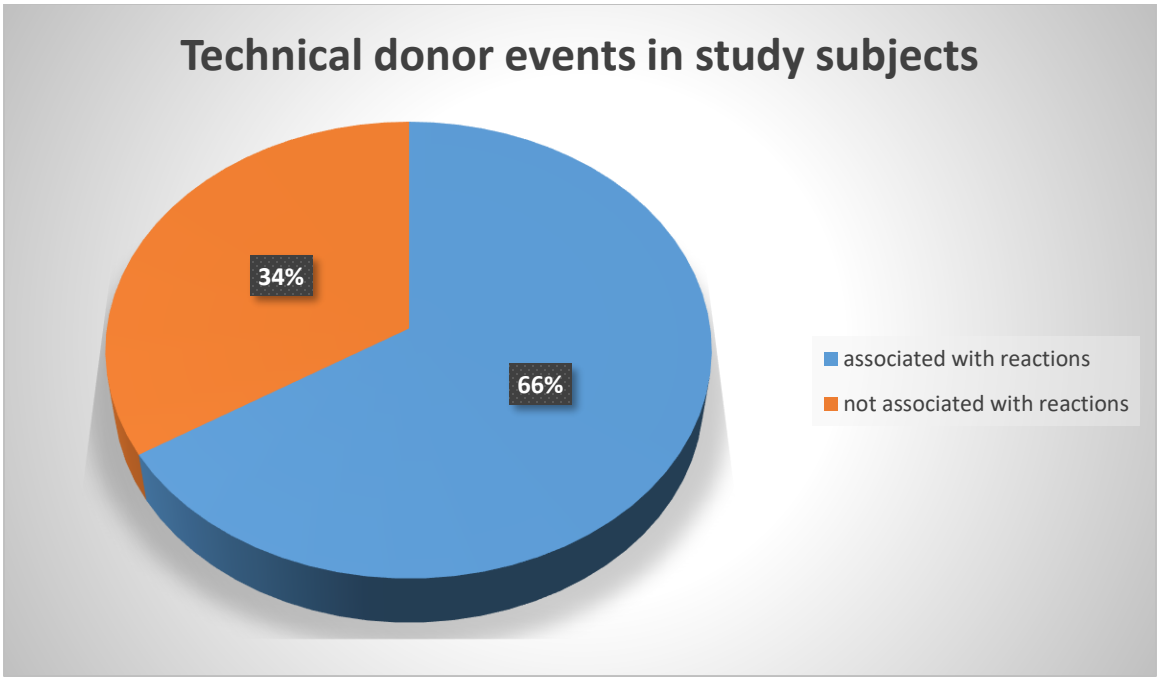


Table 15- Technical donor events in study subjects (n=62)

Technical Donor events in the study	**Number**	**Percentage**
Donor deferral	0	0
Donation discontinued due to any other reason	0	0
Significant donor history for deferral (drug intake)	2	3.22%

Failure of equipments, consumables or personnel	13	20.96%
Incorrect assembly of equipments, consumables or personnel	10	16.12%
Errors like low flow, wrong labelling, incomplete entries	23	37.09%
Anything deviating from SOP	0	0
Anything that is observed to be changed or undesirable	0	0
Others	14	22.58%

Most common technical donor event encountered in our study was errors due to low flow, wrong labeling and incomplete entries. 37.09% (23 donors) experienced these errors**.** Pre-donation counseling was another significant issue that was reported by the inhouse format.

The findings are depicted in table 15

Table 16- Imputability of Donor adverse reactions

Imputability by prescribed HvPI format	**Number of donors who developed reaction (n=224 donors)**	**Imputability by inhouse format**	**Number of donors who developed reaction (n=224 donors)**
excluded	0	0 (excluded)	0
unlikely	0	1 (unlikely)	0
possible	18	2 (possible)	18
probable	206	3 (probable)	202
certain	0	4 (certain)	4

In our study 224 donors developed reactions. Majority of cases (91%) were categorized as "probable," while 9% were classified as "Possible" by the HvPI prescribed format whereas

Table 17-AABB classification of reactions-

	No of donors as per Prescribed HvPI format	No of donors as per Inhouse Developed format
Mild	331	331
Moderate	156	156
Severe	0	4

Life threatening	0	0
Death	0	0

As per AABB classification of reactions, fall and incontinence are classified as severe reactions. Our Inhouse developed format could capture these reactions and hence report them as “severe” reactions as per AABB Classification. This was not captured by the prescribed HvPI format.

Table 18. Outcome of Donor Adverse reactions

	Number of donors with reactions	**percentage**
Resolved	213	95.08%
Follow up	11	4.9%
Resolved with sequelae	0	00
Permanent disability	0	00
Death	0	00
others	0	00

The majority of our Donor Adverse reactions (95.08%) were resolved and managed effectively. A small percentage (4.9%) required follow-up. There were no cases of reactions resulting in permanent disability, death, or other outcomes.

REACTION RATE IN OUR STUDY (n=11384)

The reaction rates noted in our study is depicted in the following tables.

Table 19. reaction rates in localized and generalized donors

	Number of donors	percentage
Local reactions	59	0.51%
Generalized reactions	165	1.44%

Table 20. reaction rates in whole blood and apheresis donors

	Number of donors	percentage
Whole blood donors	213	1.87%
Apheresis donors	11	0.09%

Table 21. reaction rates in males and females donors

	Number of donors	percentage

Males	192	1.68%
Females	32	0.28%

Table 22. reaction rates in first time and repeat donors

	Number of donors	percentage
First time donors	144	1.26%
Repeat donors	80	0.70%

Table 23. reaction rates in inhouse and camp donors

	Number of donors	percentage
Inhouse donors	184	1.61%
Camp donors	40	0.35%

DISCUSSION

Donor Haemovigilance is the systematic monitoring of both immediate and long-term adverse reactions and incidents throughout the entire chain of blood donor care. It entails identifying, reporting, investigating, and analysing adverse reactions in blood donors due to donation. This haemovigilance system is also an important component of blood system quality control, triggering corrective and preventive measures for continuous quality and safety enhancement.

The importance of blood donation always holds major importance in good transfusion services. The scarcity or shortage of blood inventory is frequently encountered in healthcare settings and is attributable to an imbalance between the increase in demand for safe blood and blood products on one hand and failure to organize regular blood supply on the other. To ensure an adequate supply of blood, collection centres must design campaigns that successfully recruit and maintain an active donor pool.

The total number of donations during the study period, including whole blood as well as apheresis were 11384 out of which whole blood donors were 10913 in number (95.86%) and 471 were apheresis donors (4.13%). Total reaction rate was 1.96%. Most of the donor reactions were seen in the age group 21 to 30 years. Reactions were more commonly seen in male donors (85.71%) as compared to female donors (14.2%). About 64% donors who experienced reactions were first time donors whereas 36% donors were repeat donors.

In the present study , we analyzed the donor adverse reactions and events in the two formats one prescribed by the HVPI and the other reported in our inhouse format . The total donor reactions reported were 224 including the whole blood as well as apheresis donation . Out of which 213 were whole blood and 11 were apheresis reactions. The inhouse format also had the ability to

capture the technical donor events which were around 62 out of which 66% of events were associated with donor reactions whereas 33 % were not associated with reactions. The total reaction rate in our study was 1.96%. reaction rates in whole blood donors was 1.87% whereas apheresis donors was 0.09%. the local complication reaction rate was 0.51 % and systemic complication reaction rate was 1.44%. first time donor reaction rate was 1.26%nwhereas repeat donors reaction rate was 0.70%. inhouse donor reaction rate was 1.61% and camp donor reaction rate was 0.35%. Reaction rates of males in our study was 1.68% whereas in females it was 0.28%. Demographic details and reaction rates found in our study corroborated with other studies (28,29) conducted previously by authors like Anila Mani et al. (16) and Rubiya et al. where they reported a reaction rate of 5.5%. (30)

Local complication were seen in 87.5 % of whole blood donors whereas only 12.5 % apheresis donors experienced local reactions. Most common local complication encountered in our study was swelling.

In our study, of all the donors who experienced systemic complications, about 95.7% of them were whole blood donors whereas only 4.3 % were apheresis donors. Most common systemic complication encountered in our study was dizziness.

Some of the complications were better reported with the help of inhouse format for donor reaction like sweating, unclear speech, fall, incontinence, and ghabrahat. These complications were not recorded by HvPI format for donor hemovigilance.

The HvPI format failed to record the technical donor events which our inhouse format was able to capture. Some of the technical donor events were associated with local and systemic complications while some were not.

In this study the donor reactions were reported in both the formats - The format prescribes by the HvPI as well as our inhouse format.

In our study 91% of donors experienced grade 1 AABB reactions whereas 9% donors experienced grade 2 AABB complications

A) Completeness of data

prescribed HvPI format	Inhouse modified format
The prescribed HvPI format • The prescribed format recorded the data in a tabular format which had no color coding. It was more complex as compared to the inhouse modified format. • Symptoms of certain systemic complications could not be recorded by the prescribed HvPI format whereas the same was possible with the help of inhouse modified format.	The inhouse modified format was easy to use as • It has a simplified format for recording the data. Even phlebotomist can record the data. • Color coding helps in easier segregation of data • Certain systemic complications like sweating, fall could be recorded by the inhouse modified format whereas they could not be recorded by the prescribed HvPI format. • Better reporting of data in the hemovigilance software resulted in better reporting of data.

	All these factors led to better data capturing and less data attrition

B) Accuracy of data

Prescribed HvPI format	Inhouse modified format
• The prescribed format didn't have any provision for monitoring the technical donor events which could have given origin to adverse donor reactions	• The modified inhouse format was more accurate in capturing the data because signs and symptoms of the complications could be recorded with the help of this format. • Addition of technical donor events helped us in finding association between technical donor events as a possible cause for the donor reactions and helped in finding out the actual cause of the reaction.

C) Assessment for grading of reaction and imputability

Prescribed HvPI format	Inhouse modified format
• Prescribed format could not record all the signs and symptoms of the	• When the donor experiences an adverse reaction, all the factors which

complications and hence could not perform better than the inhouse modified format for reporting of complications and grading of imputability as per AABB.	might have led to the adverse reaction are assessed. The modified inhouse format helped in better reporting of causes of donor adverse reactions. This resulted in better reporting of complications and grading of imputability as per AABB

The inhouse modified format of donor hemovigilance proposed in our study performed better than the prescribed format of reporting donor reactions by HvPI in the following ways-

1. With the help of inhouse modified format, we were able to report technical donor events which could have interfered with smooth operation during the donation.
2. Colour coding of the reactions helped in easier identification and reporting of events

Reporting of technical donor events helped in identifying the confounding factors which might have interfered with donation. Reporting of such events would serve as a potential to improve donation practices which in turn would lead to fewer reactions in subsequent donations. Colour coding helped in easier identification during filling the form and hence better reporting of reactions.

This provides scope for improving the efficiency of Hemovigilance program by increasing the efficiency of capturing data and reporting it.

LIMITATIONS OF THE STUDY

This study is first of its kind where we have compared a newly developed format against the prescribed HvPI format of donor hemovigilance.

1) Long term complications were not recorded in our study.
2) New staff posted in the donor area , difficulty in understanding the process of reporting the inhouse modified format was encountered.
3) Limited time period of the study.
4) Inhouse developed format was not able to report systemic reactions like anxiety and hypotension.

SUMMARY

To summarize, our study was counducted at an institute of national importance which caters to the population of central India. In our study, we compared the prescribed format of donor hemovigilance with a inhouse modified format of reporting donor reaction developed inhouse. Data was collected from all the donors who developed reaction during whole blood and apheresis donations with the help of both the format and the results were compared in terms of accuracy, completeness and assessment of data.

The modified inhouse donor reaction reporting format was able to capture the donor reactions with better efficiency and ease as compared to the prescribed HvPI prescribed format. In addition, technical donor events could also be recorded by our modified inhouse format.

CONCLUSION

This study demonstrates the efficiency and easy applicability of the inhouse modified format for donor reactions reporting as compared to the prescribed format by Hemovigilance Program of India. The format is easy to use, has separate color coding for localized and generalized symptoms which helped us in better reporting of the donor reactions which were encountered. This can be used as a valuable tool for donor hemovigilance. This will help in improving donor safety and satisfaction and will have a positive impact on the national blood supply by improving donor return rate. However the inhouse modified format failed to report certain systemic complications and their symptomatology like anxiety or hypotension. Furthermore, follow up data of the donors who developed adverse donor reaction should also be included in the format. Therefore the inhouse modified format needs extensive application to further confirm its effectivity. Further RCTs are needed to done in order to prove the effectivity of the newly developed inhouse format of donor hemovigilance.

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ANNEXURE I (HvPI prescribed format)

Annexure I

Donor Complication Form

Reference Document (Type of complication)

[] **A 1. Complications mainly characterized by the occurrence of blood outside the vessels.**

[] **a) Haematoma (bruise)**

[] Bruising/discolouration [] Redness/warmth [] Swelling [] Local pain/tenderness

[] Nerve irritation/injury

[]**b)Arterial puncture**

[] Bright Red blood [] Pulsating needle/tubing. [] Blood bag fills rapidly(< 4 min).

[] Weak pain (elbow). [] Radial pulse weak/absent.

[] **c) Delayed bleeding/ Re-bleeding)**

[] Inadequate Pressure at venipuncture site [] Inadequate duration of pressure (< 10 min)

[] Heavy lifting or strain to the donor's arm. [] Donor medications (anticoagulants/aspirin)

[] **A2. Complications mainly characterized by pain**

[] **a) Nerve injury/irritation**

[] Radiating, sharp pain moving away from the venepuncture site,

[] Paraesthesias- tingling, burning sensations in the hand, wrist or shoulder area

[] Onset of symptoms-on needle insertion or withdrawl

[] Delayed pain when accompanied by haematoma.

[] Worsening of symptoms in certain positions or with certain arm motions.

[] b) ***Other Painful arm***

[] Arm pain described as ache or heaviness in the arm(Like vaccination)

[] Absence of nerve irritation

[] **A 3. Localised infection/inflammation along the course of a vein**

Symptoms localized to phlebotomy site

[] Warmth [] tenderness [] Local pain [] Redness[] Swelling (at the site of phlebotomy)

[] Fever Present/absent

[] **a) Thrombophlebitis:** Symptoms along course of vein

[] **b) Cellulitis:** The redness, swelling and tenderness affect the soft tissues

[] **A4. Other major blood vessel injury -Serious conditions needing specialist medical diagnosis and attention**

[] **a)Deep venous throosis (DVT)** [] Swelling and Pain in upper arm [] Signs of superficial inflammation/thrombosis(See A3) [] Additional risk factor of thrombosis(ExOC pills)

[] b) **Arteriovenous fistula** [] Pulsating mass [] Palpable thrill/Associated bruit

[]Affected area-warm [] Distal area –feels cool [] Distal veins-dilated& pulsatile

[] Related to arterial puncture [] Related to venous laceration.

[] **c) Compartment syndrome** [] Painful arm [] Swelling(Haematoma) [] Paresthesias

[] **Partial** paralysis. [] Muscle and soft tissue necrosis.

[] **d) Brachial artery pseudoaneurysm**

[] Pulsating mass in the arm. [] Pain and paraesthesias.[] Haematoma(large)

[] May follow Arterial puncture (A1)

B. Complications mainly with generalized symptoms: Vasovagal reactions

→ [] Generalized Weakness [] Anxiety [] Dizziness [] Nausea [] Vomiting
→ [] Pallor (Skin and lips) [] Cold extremities [] Hyperventilation [] Hypotension [] Vomiting
[] Rapid Pulse [] Low Vol Pulse [] Feeling of warmth [] Vomiting
[] Convulsions [] Tetany [] Twitching [] Vomiting

a) [] LOC (Loss of Consciousness)< 60 sec b) [] With Injury c) [] Within Blood collection facility [] LOC (Loss of Consciousness) > 60 sec [] without injury [] Outside blood collection facility [] Without loss of consciousness (LOC)

C. Complications related to apheresis

[] a) Citrate reaction

[] Numbness/tingling/vibrations-lips, fingers [] Metallic taste [] Vomiting
[] Chills/ shivering [] light-headedness [] Muscle twitching [] Carpopedal spasm
[] rapid or slow pulse, [] Irregular Pulse [] shortness of breath.
[] Tetany(generalized muscle contractions) [] Shock [] Cardiac arrest

[] b) Haemolysis

[] Pink or red plasma [] Blood in lines [] Pink or red urine

[] c) Air embolism

[] Bubbling sound or feeling at venipuncture
[] Cough [] Dyspnea [] Apprehension [] Sweating [] Chest pain [] Confusion
[] Tachycardia, [] Hypotension,[] Nausea [] Vomiting.

[] d) Optional category: Infiltration of IV fluids []-Swelling at venipuncture site

D. Allergic reactions

[] a) Allergy (local)

[] Itching and redness at the ()venepuncture site ()Bandage site or () Skin disinfection area. [] Raised rash or hives that may expand to cover a larger area of the arm.
[] Occurrence ()Soon after donation () Hours later () Days later.

[] b) Generalised allergic reaction (anaphylactic reaction)

[] Occurs soon after reaction[] Cardiac arrest
[] Apprehension/Anxiety[]Flushing,swellingof eyes, lips or tongue[] cyanosis [] cough
[]wheezing [] Dyspnea [] Chest tightness [] cramps, nausea, vomiting, diarrhoea,
[] tachycardia [] Hypotension [] altered mentation.

E. Other serious complications related to blood donation

Major cardiovascular event (MCE) (Upto 24hours after donation.

a)[] Acute cardiac symptoms (other than myocardial infarction or cardiac arrest).
b)[] Myocardial infarction(MI) c) [] Cardiac arrest []Transient Ischemic Attack(TIA)
d)[] Cerebrovascular accident e) [] Death

IMPUTABILITY LEVELS (Grading of complication severity and Imputability strength of relation between donation and complication)

The Imputability levels are given below:

- **Definite (Certain):** when there is conclusive evidence beyond reasonable doubt for the relation.
- **Probable (Likely):** when the evidence is clearly in favour of a relation.
- **Possible:** when the evidence is indeterminate for attributing the complication to the donation or an alternative cause.
- **Unlikely (Doubtful):** when the evidence is clearly in favour of attributing complication to other cause.
- **Excluded:** when there is conclusive evidence beyond reasonable doubt that the complication can be attributed to causes other than the donation.

Denominator Data About All Donor	
1. Total donations in the month (of reporting)	
Whole blood[ ] Apheresis[ ] If apheresis RBC[ ] Platelets[ ] Plasma [ ] Plasma + Platelets[ ]	
2. Gender of Donor (Total) Male [ ] Female [ ]	
3. Donor Types (Total) First-time donors [ ] Repeat donors [ ]	
4. Volume of donation	
No of 350 ml donations [ ] No of 450 ml donations[ ]	others

Adverse Blood Donor Reaction Reporting Form

I) Donor Information

Donor Id: _____

Sex _____

Weight of Donor (KG) _____

Age/Date of Birth _____

Type of Donation (a) Whole Blood
(b) Apheresis — (1 RBC 2 Platelets 3 Plasma 4 Plasma + Platelets
Donor Type (a) Voluntary, (b) Replacement, (c) Voluntary Family Donor
(1 first time 2 repeat)
Venipuncture (a)-1, (b) 2-(c) >2
Data Captured (a) Onsite, (b) Call back by donor, (c) Call back by Blood Centre
Site of Donation (a) Camp (b) Blood Centre

II) Details of Blood Collected

Lot No. of Blood Bag _____
Manufacturer of Blood Bag _____
Date & Time of Donation _____

Volume of Blood Collected (ml) _____
Expiry date of Blood Bag _____
Date & Time of Reaction _____

III) Type of Complications (Refer Annexure I)

A1-Complications mainly characterized by the occurrence of blood outside the vessels
- (a) Haematoma (bruise)
- (b) Arterial puncture
- (c) Delayed(bleeding/Re-bleeding)

A2-Complications mainly characterized by pain
- (a) Nerve injury/irritation
- (b) Other Painful arm

A3-Localised infection/inflammation along the course of a vein
- (a) Thrombophlebitis
- (b) Cellulitis

A4- Other major blood vessel injury -Serious conditions needing specialist medical diagnosis and attention
- (a) Deep venous thrombosis (DVT)
- (b) Arteriovenous fistula
- (c) Compartment syndrome
- (d) Brachial artery pseudoaneurysm

B-Complications mainly with generalized symptoms: Vasovagal reactions
- (a) LOC(Loss of Consciousness) < 60 sec
- (b) LOC(Loss of Consciousness) > 60 sec
- (c) Without loss of consciousness (LOC)
- (d) With injury
- (e) Without injury
- (f) Within Blood collection facility
- (g) Outside blood collection facility

C-Complications related to apheresis
- (a) Citrate reaction
- (b) Haemolysis
- (c) Air embolism
- (d) Infiltration of IV fluids

D-Allergic reactions
- (a) Allergy (local)
- (b) Generalised allergic reaction (anaphylactic reaction)

E-Other serious complications related to blood donation
- (a) Acute cardiac symptoms
- (b) Myocardial infarction(MI)
- (c) Cardiac arrest
- (d) Transient Ischemic Attack(TIA)
- (e) Cerebrovascular Accident
- (f) Death

F-Other Reactions.....

IV) Outcomes

- ☐ Resolved
- ☐ On Follow Up
- ☐ Recovered with Sequelae
- ☐ Permanently Disabled
- ☐ Death following the Adverse Reactions
- ☐ Unknown

V) Imputability (Refer Annexure II)

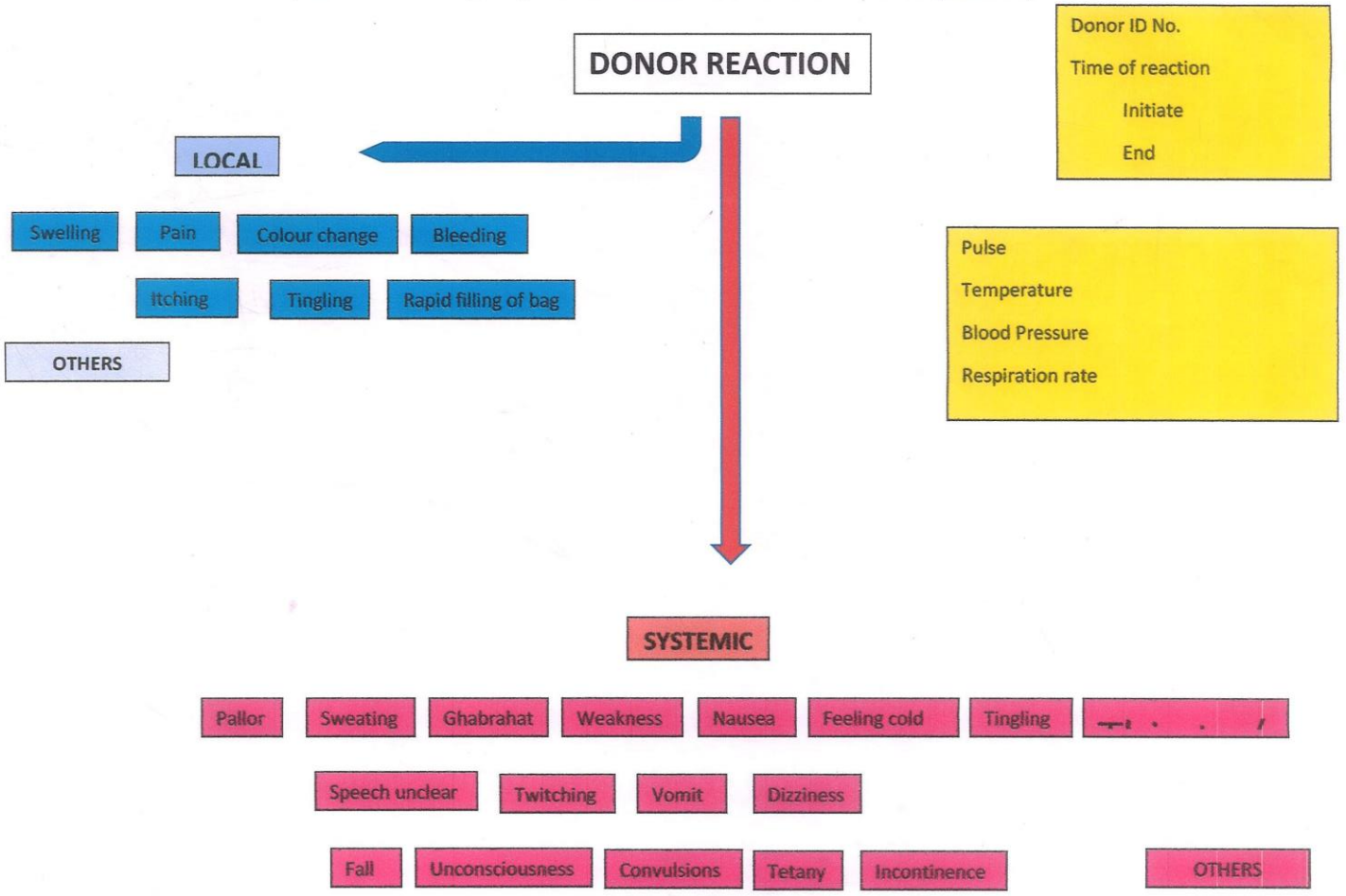
- ☐ Definite (Certain)
- ☐ Probable (Likely)
- ☐ Possible
- ☐ Unlikely (Doubtful)
- ☐ Excluded

ANNEXURE II (Inhouse developed format)

A) DATA from Donor Registration Card – No need to repeat

a. Sex
b. Weight
c. Date of Birth
d. Type of donation: whole blood / apheresis
e. First time or Repeat donor
f. Voluntary or Replacement or Family voluntary donor
g. Bag details: Lot No. Volume collected, date and time of collection
h. Donation site: blood bank or Camp
i. No. of venipuncture
j. Baseline parameters of Pulse / Temperature / respiratory rate

B) New format for capturing data about donor reaction & donor area events **(Encircle)**



C) Technical Donor Events

Definition: Technical problems related to equipment, staff or environment that impairs the procedure and may not necessarily affect the successful collection of donated blood or result in a donor reaction

a. Donor deferral
b. Donation discontinued for any reason other than reaction eg. urgency, unwilling
c. Significant donor history for deferral
d. Failure of equipment, consumable or personnel
e. Incorrect assembly of equipment, consumable, or personnel
f. Errors like low flow, wrong labelling, incomplete entries
g. Anything deviating from the SOP
h. Anything that is observed to be changed or undesirable
i. Others

Describe – in your own words

D) Evaluation of DATA

As per HvPI and AABB hemovigilance directions

Type of reaction:

Local

Systemic

Event

List out Treatment given

-
-
-
-
-

1. **Outcome**

Resolved	Follow up	Recovered with sequelae	Permanent disability	Death

OTHERS

2. **Grading of Imputability**

4	3	2	1	0
Definite / Ceratin	Probable / Likely	Possible	Unlikely / Doubtful	Excluded

3. **Grading**

AABB

HvPI